

RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects and Animals in Navy Research

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Comment

The DON HRPP Site Visit

One of the DON HRPP's missions is to monitor commands to ensure continued compliance with their Assurances - their "promise" to uphold the ethical principles and regulatory requirements for protecting human research subjects. The DON HRPP can't carry out this mission by reviewing documents alone. For that reason, in recent months the team has gone on the road, visiting seven Navy sites that conduct human subject research.

The site visits typically take two to three days. They consist of in-depth interviews with research directors, chairs and members of Institutional Review Boards (IRBs), investigators, and other staff supporting research. Time permitting, DON HRPP subject-matter experts lead training sessions tailored to the command's researchers, IRB chairs and members, and other command staff.

Prior to visiting sites, the DON HRPP team reviews IRB minutes, research protocols, the command's HRPP instruction and SOPs, and other pertinent documents. Visits conclude with a concise outbrief for the commanding officer on findings and suggestions for improvement, if any. The site-visit team then provides a follow-up report to the CO and his or her HRPP team.

The site visit is intended as a rigorous evaluation of the command's performance in protecting human subjects—the HRPP mission. Yet the team does not approach site visits looking for deficiencies. Two years ago, Navy leadership reorganized the human research protection program and declared a renewed commitment to human research protection. The policymaking, organizational, and management challenges since then have demonstrated that the HRPP mission is quintessentially one of education and support for commands that are conducting research urgently needed by Fleet/Force personnel and their families.

The HRPP staff is aware that Navy researchers are seeking to ensure the well-being of subjects. All the sites visited thus far have demonstrated an impressive commitment to the welfare and safety of research subjects.

The site visit program, then, isn't intended to single out commands that seek guidance on getting their policies and practices right. It aims to remind them that the DON HRPP offers the guidance they need to comply with the requirements for research protections. For example, documentation requirements may appear burdensome, yet they are

essential for clear communication among investigators, IRBs, and command personnel supporting research. Some requirements simply parallel the evolution of complexity in many areas of Navy research and reflect increasing collaborative research among the three sister services and more partnerships with our civilian counterparts.

Most importantly, site visits are opportunities for the DON HRPP team to observe a command's HRPP in action, talk about issues directly relevant to each command, and share the experiences and "good practices" found during site visits elsewhere.

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2007 Navy-Wide Academic Research Competition

Larys and Bushey Take Top Honors at Research Competition

Cmdr. Robert Larys and Lt. Cmdr. Brent Bushey, won the 2007 Navy-wide Academic Research Competition, held at the Naval Medical Center San Diego, on May 18.

The top winners continue a tradition started twenty-two years ago by Capt. Steve Amis, MC, Commanding Officer of National Naval Medical Center (NNMC). In 1986 NNMC hosted the inaugural Navy-wide competition with one resident investigator from each of the then four teaching hospitals (NNMC Bethesda, NMC Oakland, NMC Portsmouth and NMC San Diego) vying for the top honor.

The competition's success led to expanding its scope in 1989 to include staff/fellows. The winning resident's command displayed the competition plaque and hosted the following year's Navy-wide competition. Beginning in 1996, separate plaques for resident and staff winners were displayed at the winners' command for the ensuing year.

Cmdr. Larys' research in the resident category, "The Effect of High Altitude on the Visual Acuity and Refractive Error of Post-LASIK Corneas," found LASIK safe, effective, and advantageous for naval aircrews. His work prompted policy changes and further research involving required vision correction for current naval aircrew and individuals seeking naval aircrew designation. Lt. Cmdr. Bushey's staff-level work, "Evaluation of Lipid Emulsion for Resuscitation of Bupivacaine-Induced Cardiac Toxicity in Awake Swine," explored using a lipid solution to treat potentially dangerous complications during anesthesia recovery in swine and contributed to further understanding of anesthetic agents.

NMC San Diego's Deputy Commander Capt. Paul Pearigen launched the competition and welcomed the presenters, guests and judges. He emphasized the importance of research relevant to warfighters at the "tip of the spear."

Rear Adm. Christine Hunter, Commander, NMC San Diego, presented the plaques. No stranger to the academic research competition, Hunter noted that she knows what it feels like to hold this honor—she won the staff category in 1988 as a Hematology/Oncology fellow at NMC San Diego.

Lt. Cmdr. Francisco Gutierrez of Naval Medical

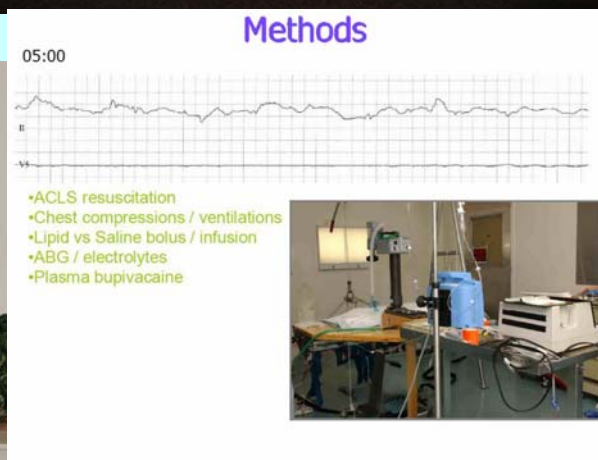
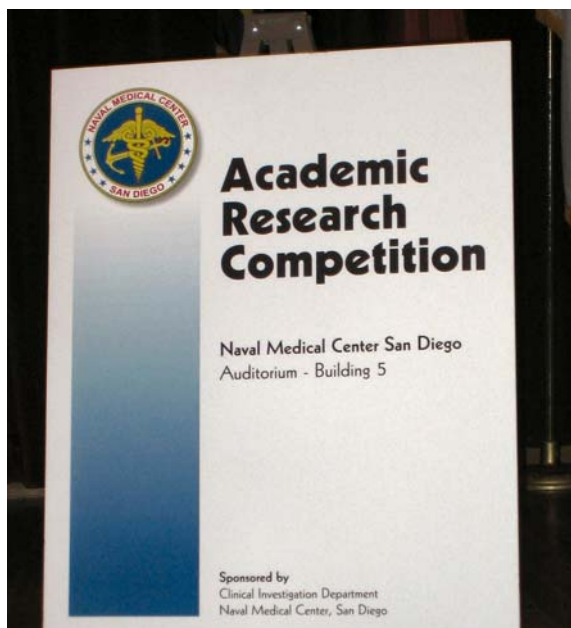
Center Portsmouth (NMCP) and Lt. Cmdr. Jonathan Forsberg of the National Naval Medical Bethesda (NNMC) also competed in the resident category. The other staff competitors were Lt. Cmdr. Gregory Gorman of NNMC who presented his research via teleconference from Kuwait and Lt. Cmdr. Buddy Kozen of NMCP. The research included the epidemiology of hemodialysis in children, comparing methods for controlling severe bleeding, laboratory tests that might aid in predicting wound healing, and quick, yet cost-effective treatment for migraine headaches.

Although initially focused on medical residents and staff, nurses and allied health care providers participated in later competitions. At the 14th annual competition, in 1999, Lt. Cmdr. (now Capt.) Joseph Pellegrini, NC, USN, from the Anesthesiology Department at NMC Portsmouth, took top honors in the staff category. In 2004 Lt. Rex Watson, MSC, USNR, from NMC San Diego's Laboratory Department, scored first place in the staff category.



The judges rated the written abstracts and challenged the presenters with tough questions after the oral presentations before making a decision. Speaking on behalf of the judges, Dr. Stephen L. Farrow, a Veterans Health Care System physician, encouraged the audience to be inquisitive and continue novel work pertinent to the warfighter.

Dr. Farrow remarked on the difficulty of the judges' decision as each researcher's work was clearly "the best of the best." The other competition judges were Dr. Guy Banta, former Commanding Officer, Naval Health Research Center, San Diego, and currently President & CEO of Eagle Applied Sciences, LLC, San Antonio, TX; and Ms. Marianne Elliott of the DON HRPP staff.

2007 Navy-Wide Academic Research Competition**Around the Research Competition****Impact**

- Results presented to BUMED Aviation Advisory Committee on 8 Dec 2006
- Initial study of 30 Class 2 aviators immediately authorized (Return to Flight Study)
- Follow on study of 300 Class 1 and 2 aviators also authorized (accession arm included)
- General authority for aeromedical waivers



Research Protection Education

Navigating CITI: Taking the Right Course

The two most common problems we see among DON CITI learners are that they 1) choose the wrong learner group, or 2) complete multiple courses. Typical examples of choosing the wrong learner group include investigators completing the modules intended for Directors, Department Chairs, Programs Managers, etc., or IRB members completing the modules required of the Scientific Reviewer group. Completing multiple courses isn't necessary, because each learner group reflects appropriate material based on one's role in research.

In the first case, above, the learners are not taking the appropriate training. The modules actually taken (e.g., investigator completing Directors, Department Chairs, Program Managers, etc. modules) are not comprehensive enough to cover the actual role of investigator or IRB member. Even with completion report in hand, the investigator or IRB member is not in compliance with DON requirements and, therefore, neither is the command. Descriptions of all currently-available role-based learner groups and requirements are included as part of DON HRPP's Education Policy, which is posted on our web pages—click on the Education and Training link at <http://navymedicine.med.navy.mil/humanresearch/>.

Not surprisingly, hard-charging Navy learners often complete more than one basic course of study at CITI. This "problem" in the second case, above, may reflect some confusion about training requirements. Most of-

ten, people are completing both Biomedical (BIO) and Social Behavioral (SBR) tracks for the same learner group. In developing the learner groups, DON HRPP was careful to include comprehensive information on SBR in the BIO track, because there is often overlap of the two disciplines in BIO research. On the other hand, BIO components in SBR research are comparatively rare, so the SBR track does not convey BIO information.

How to choose? If you do only biomedical research or both BIO and SBR, select the BIO track. If you are involved only in SBR research, register for the appropriate learner group in the SBR track. If you're not sure, email us at human.research@med.navy.mil

Each command has the option of increasing or augmenting minimum requirements for human research protection education, and every command is responsible for documenting that its members are adequately trained. Administrators should scrutinize training certificates to ensure that each learner completes the most comprehensive course of study for his or her role in the command's human research protection program.



Our e-mail address has changed. DON HRPP is no longer humanresearch@us.med.navy.mil; now we're human.research@med.navy.mil. Just put a dot between the 'human' and 'research' and take the 'us' out after the '@'. Not big changes, but please make them so we can stay in touch.

We Need Your Help!



Have a "Good News" story from your Research Protection Program?

Don't keep it to yourself. Why not share it with the DON Research

Protection community? We're looking for material to publish in the *Research Protections Update* newsletter.

Send your research news, success stories, tips, pictures,

lessons learned, or other material related to the ethical conduct of

human or animal research to human.research@med.navy.mil.



Get a BZ from RPU!

DON Animal Research Protection

Site Visits: The Veterinary Perspective

By Col. Mark Gold

If you read Thomas Friedman's *The World is Flat*, you would know that globalization is an inevitable feature part not only of our future, but also of our present.

Outsourcing and off-shoring clearly are at play in animal-based research and care, as in many industries. The list of facilities using contracted animal care is long, as is the list of laboratories conducting government research under contract, grant, collaboration, or other agreement.

We know what it takes to provide the highest quality of oversight and care for our own animals—all of our facilities are accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC). The *Animal Welfare Act Regulation* (9 CFR) provides minimal standards for animal facilities in the U.S. Some facilities meet higher standards such as those in the *Public Health Service Policy on Animal Care* and have Office of Laboratory Animal Welfare (OLAW) assurance; still others are AAALAC accredited. But to what standard can we hold our collaborators? Our joint regulation, SECNAVINST 3900.38C, AR 40-33, provides guidance on these responsibilities, but needs some clarification.

Our review is to ensure that DoD sponsors only legal, high-quality animal care.

In the instruction, "DoD veterinarians trained or experienced in laboratory animal medicine and science ..." are tasked with administrative review and approval of all proposed animal care under contracts or grants. If the proposed research involves work with nonhuman primates, dogs, cats, or marine mammals; or if the research procedures, program, or conditions warrant, the veterinarian also must conduct a site visit of the facility.

At what level is this visit conducted? What is an administrative review? And what are the conditions that

warrant a site visit?

Army Veterinary Corps Officers assigned to DON facilities clearly meet the training or experience criteria. Other veterinarians serving the DON should look to their respective Institutional Animal Care and Use Committees (IACUCs), Commanding Officers, and/or the BUMED Director of Veterinary Affairs for guidance. Since the SECNAVINST does not stipulate that the "component office" (i.e., BUMED) perform this review, DON commands are free either to perform these duties themselves, delegate them to subordinate commands, or send them to the Veterinary Affairs Office at BUMED. Regardless of who performs this review and/or site visit, BUMED will review all reports generated during component-level compliance visits.

An administrative review should not undermine the deliberative actions of a duly constituted IACUC or attempt to re-write a protocol. The review should ensure that the protocol addresses completely every section of the DoD animal-use protocol template in accordance with the guidance provided.

Our review is to ensure that DoD sponsors only legal, high-quality animal care. Our decision on whether or not to do a site visit depends on how effective a program is in conducting appropriate research. Giving objective guidance on what constitutes a significant problem or what study topic warrants a site visit is nearly impossible.

Researchers and research officials should consult with their commanding officers, public affairs officers, and IACUCs, or the Office at Veterinary Affairs at BUMED for further guidance. Should a site visit be necessary, the minimum standard is 9 CFR. A formal report is required for the Command, BUMED review, and potentially for release under the Freedom of Information Act.

Col. Mark Gold, USA, is Director of Veterinary Affairs in the Office of Research Protections at the Bureau of Medicine and Surgery.